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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/680,716 | 10/06/2003 | Tuoc Tan Nguyen | 816020-100045-US | 2647 |
| 34026 | 7590 | 04/19/2005 | EXAMINER | |
| JONES DAY | | | MILLER, CHERYL L | |
| 555 WEST FIFTH STREET, SUITE 4600 | | | ART UNIT | |
| LOS ANGELES, CA 90013-1025 | | | PAPER NUMBER | |
| | | | 3738 | |

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/680,716

Applicant(s)

NGUYEN ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of species 4, drawn toward figure 14 is acknowledged by the examiner.

Claim Objections

Claim 1 is objected to because of the following informalities: Line 6 recites, "near the *inflow annulus of a valve sinus* to an attachment location within a *sinus cavity*". Appropriate correction is required. A valve sinus and sinus cavity have not been introduced in the claim. It is unclear whether applicant is trying to claim part of the valve assembly structure or refer to portions of the body. An inflow annulus of the replacement valve has already been claimed in line 2 and it is unclear whether the inflow annulus in line 6 is referring to the same or different annulus.

Claim 5 is objected to because of the following informalities: Line 2 recites, "the sinus commissural posts". Appropriate correction is required. It is unclear whether applicant is referring to a portion of the body (portion of the native valve) or a portion of the valve assembly replacement valve.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 and 5-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Gabbay (US 2003/0040792 A1). Gabbay discloses an assembly (fig.2, 4, 14, 18) comprising a replacement valve (12, 472, 590) having leaflets (22, 24, 26; 480) and a scalloped inflow annulus (inflow annulus is shown to be scalloped in all figures, but most clearly seen in figs. 1, 4, 15, 24) and an expandable anchoring structure (14, 420) having flared rims (see fig.15, 18, 14, 11, 2) and a plurality of support posts (any element seen in red in attachment 1) extending between the rims. Gabbay discloses the valve (12, 472, 590) to be positioned internal of the anchor structure (see figs). Gabbay discloses support posts to comprise a triangular window (attachment 1) *capable* of accommodating tabs. Gabbay discloses the support post to extend beyond the outflow rim (in the form of barbs 66, 70; see fig.3). Gabbay discloses the inflow rim of the anchor structure to have one or more rings in undulating patterns and the outflow rim to comprise one or more rings in an undulating pattern connected by a vertical element (see attachment 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seguin et al. (US 2004/0093060 A1) in view of Myers et al. (US 2002/0052651 A1). Referring to claim 1, Seguin discloses a valve assembly comprising a replacement valve ([0023] and seen

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for example in fig.37 and 38 as 312) having an inflow annulus, an outflow annulus, and a plurality of leaflets in between the inflow and outflow annulus (fig.37, 38), and an expandable and collapsible anchoring structure (stent frame seen in figure 13, 17, 18, 19, 21, and 22 for example) dimensioned to extend longitudinally from an inflow attachment location to an outflow attachment location and having flared rims (fig.17, 21, 36, 37). Seguin however, has shown the valve inflow and outflow annulus to be straight rather than scalloped. Myers teaches in the same field of valve assemblies, the use of scalloped inflow and outflow annuluses on replacement valves like the one of Seguin (see figures 8, 9, 17, 28, and 29), as an improvement to straight annuluses, in order to provide increased hemodynamic performance, minimized creasing, and an overall better fit within the native valve [0088-0090]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Seguin's valve prosthesis, with Myers teaching of scalloping annuluses of valve prostheses, in order to provide increased hemodynamic performance, minimized creasing, and an overall better fit within the native valve.

Referring to claims 2, 5, and 10-17, Seguin discloses a valve place internal of the anchor structure (fig.37, 38). Seguin discloses the inflow rim to comprise a plurality of rings (104, 103) in an undulating pattern connected by a vertical element (105; see fig.19). Seguin discloses the outflow rim to comprise a plurality of rings (114) in an undulating pattern connected by a vertical element (115; see fig.18). Seguin discloses the inflow rim to comprise barbs (107; fig.19).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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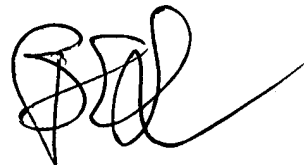
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller

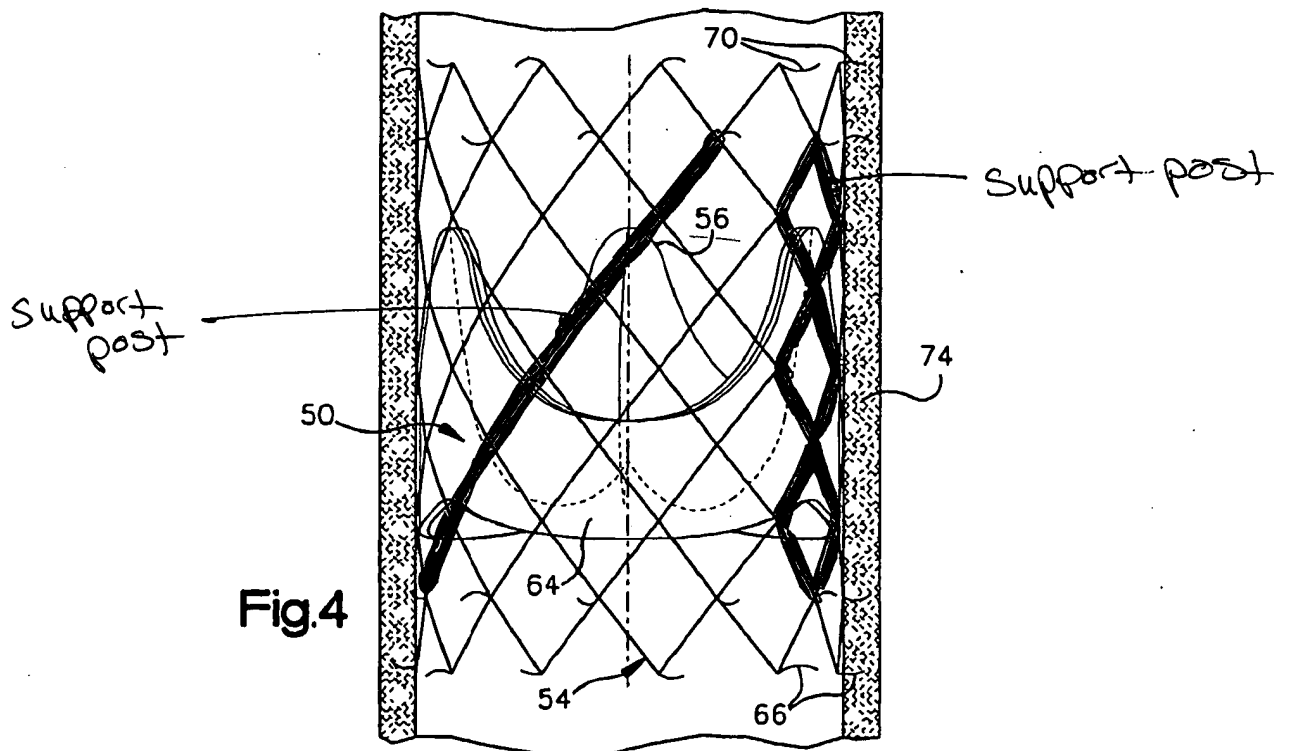
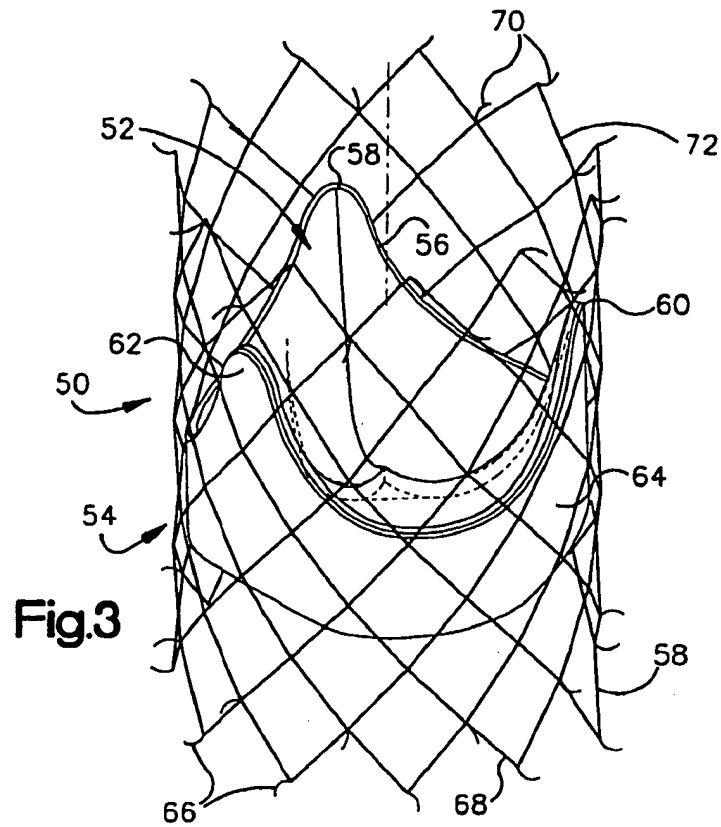


BRUCE SNOW
PRIMARY EXAMINER

Attachment # 1 (marked up)

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Attachment # 1 (marked up)

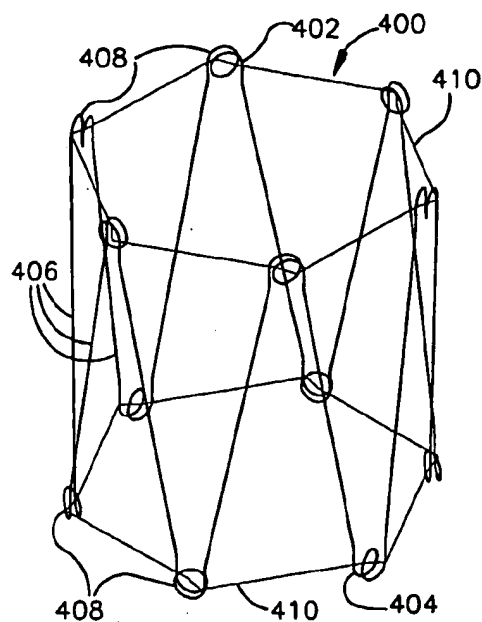


Fig. 12

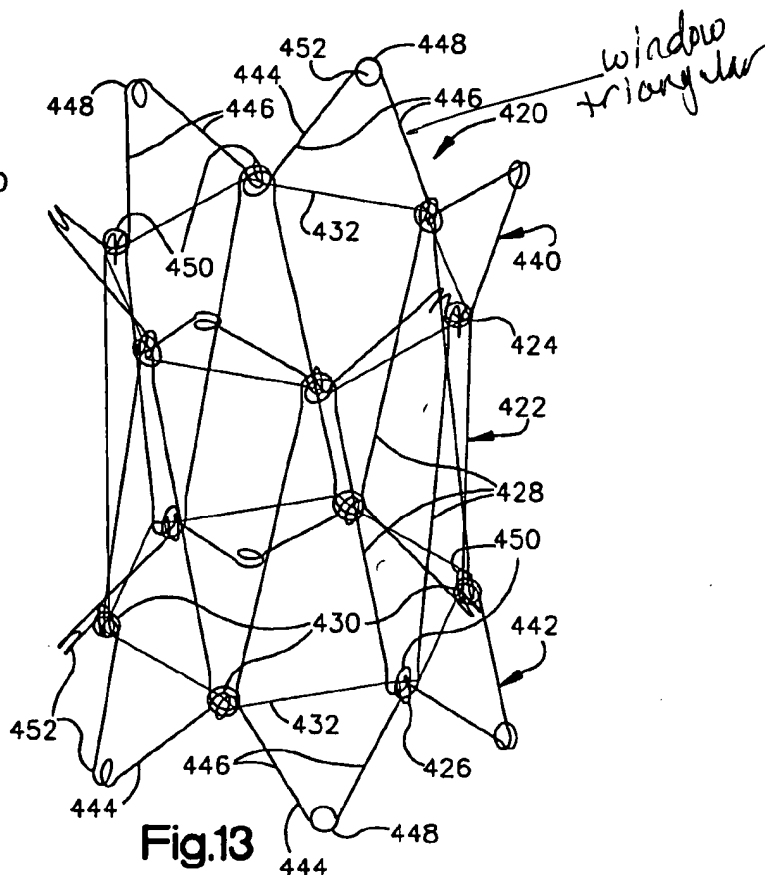


Fig. 13

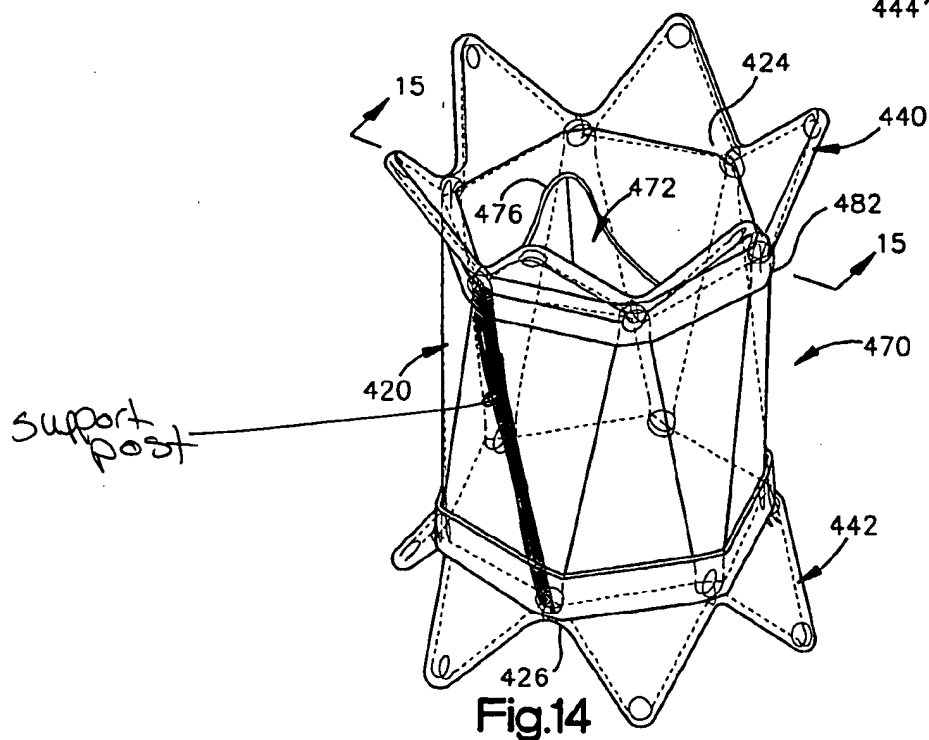


Fig. 14

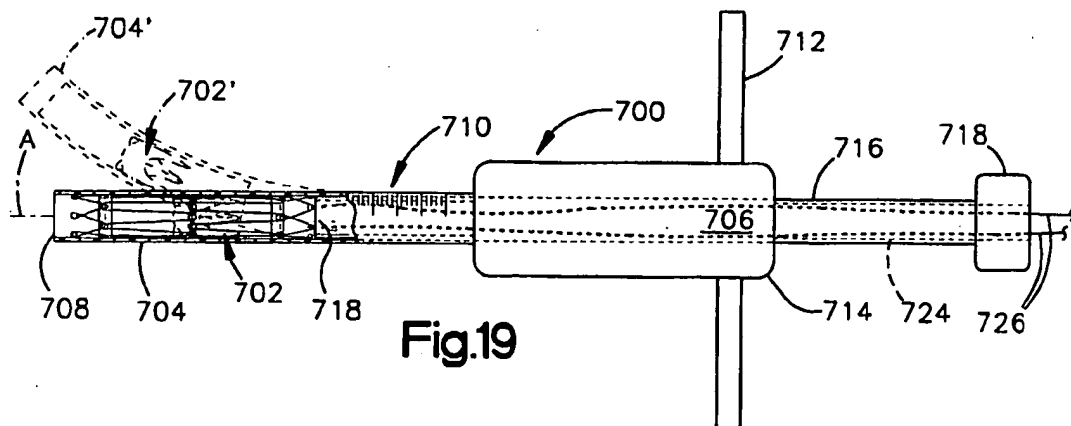
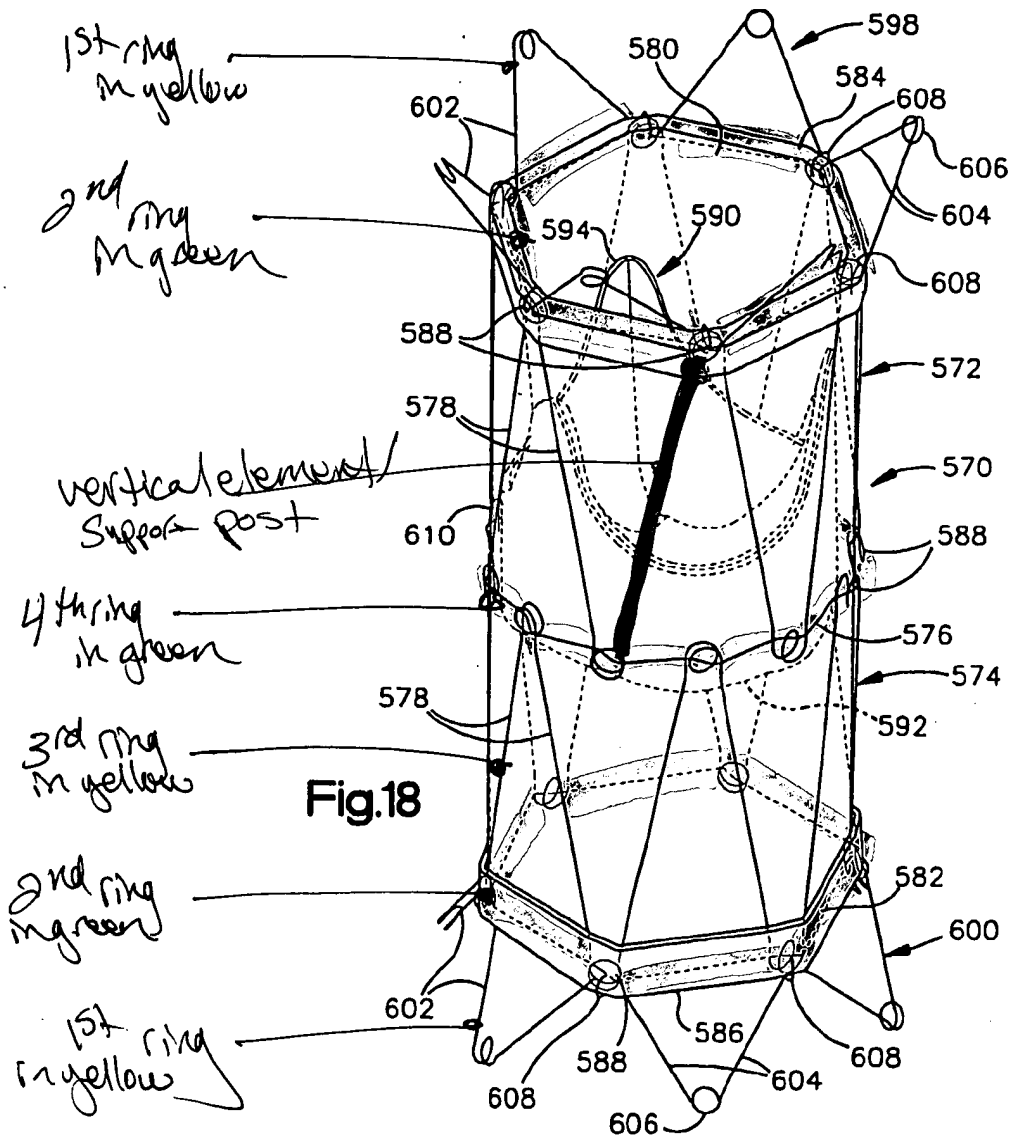
Attachment #2 (marked up)

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Attachment #2 (marked up)

